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| 10/532,021 | 01/17/2006 | Elka Toutou | P-6249-US | 6151 |
| 49443 7590 03/28/2008 Pearl Cohen Zedek Latzer, LLP 1500 Broadway 12th Floor New York, NY 10036 | | | | |
| EXAMINER | | | | |
| VENC1, DAVID J | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1641 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/532,021

Applicant(s)

TOUITOU ET AL

Examiner

David J. Venci

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on October 19, 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 71-93 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 71-93 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SE/US)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Unity of Invention

Restriction to one of the following inventions is required under 35 U.S.C. 121 and 372:

- I. Claims 71 and 73-76, drawn to cell-based assays with pharmacologic endpoint
- II. Claims 72, 77-80 and 92, drawn to cell-based assays with concentration endpoint
- III. Claims 81-91, drawn to devices and systems thereof
- IV. Claim 93, drawn to cell-based assays for optimizing therapeutic efficacy

According to PCT Rules 13.1 and 13.2, inventions must form a single general inventive concept by sharing a common technical feature that contributes over the prior art. However, Inventions I through IV do not form such a single general inventive concept because the technical feature common to Inventions I through IV does not contribute over the prior art.

Specifically, the device of Invention III is used in the methods of Inventions I, II and IV.¹ However, Rotman (US 4,734,372) describes all the elements of the device of Invention III, including a donor compartment (see Fig. 2, cavity 48), a receiver compartment comprising cells (see Figs. 1 and 2, cell compartment 20), and a membrane (see Figs. 1 and 2, membranes 22 and 24) located between the donor and receiver compartments.

Therefore, unity of invention is lacking because Inventions I through IV do not form a single general inventive concept by sharing a common technical feature that contributes over the prior art. In

¹ Examiner requires restriction between product and process claims. Where Applicant elects to prosecute claims directed to a product, and the product claims are subsequently found allowable, Examiner will consider withdrawing the instant restriction requirement and rejoining non-elected, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claims (*i.e.*, all the process claims must include all the limitations of the allowable product claims). Examiner will not rejoin non-elected, withdrawn process claims that are not commensurate in scope with the allowable product claims. See MPEP § 821.04(b). Thus, where Applicant elects to prosecute claims directed to a product, Examiner advises Applicant to continually amend the non-elected, withdrawn process claims during prosecution to require all the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoiner.** Upon rejoiner, Examiner will fully examine the rejoined process claims in accordance with 37 CFR 1.104 for compliance with all criteria for patentability, including the requirements of 35 U.S.C. 101, 102,

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accordance with 37 CFR 1.499, Applicants are required, in reply to this action, to elect a single invention to which the claims must be restricted.

This application contains claims directed to the following species:

1. Select ONE "hydrophobic layer" from:

- | | |
|--|--------------------------------|
| a. collagen and glycosaminoglycan; | (claims 81, 83, 84, 87 and 88) |
| b. SILASTIC®, silicone; | (claims 81, 83-86, 88 and 89) |
| c. ceramides; | (claims 81, 83, 84 and 89) |
| d. cholesterol, cholesteryl esters, cholesterol derivatives; | (claims 81, 83, 84 and 89) |
| e. phospholipids; | (claims 81, 83, 84 and 89) |
| f. free fatty acids, esters of free fatty acids; | (claims 81, 83, 84 and 89) |
| g. cellulose acetate membrane, pure cellulose acetate; | (claims 81, 83, 84 and 89) |
| h. cellulose nitrate; | (claims 81, 83, 84 and 89) |
| i. polysulfone membrane; | (claims 81, 83, 84 and 89) |
| j. glass fiber; OR | (claims 81, 83, 84 and 89) |
| k. TEFLON®. | (claims 81, 83, 84 and 89) |

2. Select ONE apparatus "form" from:

- | | |
|-------------------------------------|--------------------|
| a. sack, teabag, pocket, container; | (claims 81 and 90) |
| b. tube, container; OR | (claims 81 and 90) |
| c. plate, dish, container. | (claims 81 and 90) |

Applicants are required under 35 U.S.C. 121 and 372 to elect ONE species from each of species groups 1 and 2, *supra*. Examination on the merits shall be restricted to Applicants' elected species so long as generic claims 71, 72, 81, 92 or 93 are under rejection. Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of the allowable generic claim as provided by 37 CFR 1.141.

The members of species groups 1 and 2 appear to lack a common special technical feature required under PCT Rule 13.2. For example, the members of species group 1 lack unity of invention because each "hydrophobic layer" has a different composition with different permeability characteristics. The

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members of species group 2 lack unity of invention because each apparatus "form" appears to have a different conformation resulting in different rheological and filtration characteristics.

Applicants are advised that a complete reply to this requirement must include: (i) an election of an invention and species to be examined, even if the requirement is traversed² (37 CFR 1.143), and (ii) identification of the claims encompassing the elected invention and species. An argument that claims are allowable or that all claims are generic is considered non-responsive unless accompanied by a complete election.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is (571)272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

apply where Examiner withdraws the restriction requirement before the patent issues. See MPEP § 804.01.

² Applicant may elect an invention or species with traverse or without traverse. To reserve a right to petition, Applicant must elect *with traverse*. Should Applicant traverse on the ground that the inventions or species are not patentably distinct from each other, Applicant should clearly admit on the record, or submit or identify evidence already on the record that the inventions or species are obvious variants over each other. However, if Examiner finds one invention or species unpatentable over prior art, Examiner may use the evidence or admission of record to reject other inventions or species under 35 U.S.C.103(a). If Applicant elects *with traverse* but does not distinctly and specifically point out supposed errors in this restriction requirement, then Applicant's election is considered incomplete and treated as an election *without traverse* pursuant to MPEP § 818.03(a). Failure to timely argue in support of traversal will result in the loss of right to petition under 37 CFR 1.144.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

David J Venci
Assistant Examiner
Art Unit 1641

/Long V Le/
Supervisory Patent Examiner, Art Unit 1641